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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,882	08/08/2003	Benjamin Spenser	501015.20512	2524

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EXAMINER
MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
3738	

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DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/637,882	SPENSER ET AL.	
	Examiner	Art Unit	
	William H. Matthews (Howie)	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36 and 39-71* is/are pending in the application.

4a) Of the above claim(s) *12,13,23,24,27,28,31,32,34,35 and 41-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14-22,25,26,29,30,33,36,39,40,70 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-14-03,8-8-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (valve device) and specie I-a, II-a, and III-a in the reply filed on 1-17-06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 12,13,23,24,27,28,31,32,34,35, and 41-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Note Applicant listed claim 67 as withdrawn in the Election, but "(original)" in the claim listing.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 16,29, and 30 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1,28, and 29 of prior U.S. Patent No. 6,893,460. This is a double patenting rejection.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-11,14,15,17-22,25,26,33,36,39,40,67,70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11,14-21,24,25,28,29 of U.S. Patent No. 6,893,460. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims are broader than the patented '460 claims.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 29,36, and 70-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 1 of claim 29 recites "the main body" which lacks proper antecedence.

Claim 36 is indefinite because line 11 recites "rigid support beams" which are also defined in line 7. Therefore it is unclear if the second recitation is a new element or a further limitation to previously defined element.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7,10,11,14-18,36,39,40, and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Schreck US PN 6,454,799.

Schreck discloses in figures 1-3, lines 16-65 of col. 6, and lines 33-63 of col. 7 a tricuspid heart valve comprising annular stent 24, equidistantly spaced rigid support beams 42 with bores 56,80 for stitching, and leaflets 32 of biological tissue or synthetic polymers (PET).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 8,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Boretos et al. US PN 4,265,694 or Wheatley et al. US PN 6,171,335.

Schreck meets the structural limitations of claims 8 and 33 as described above, but lacks the express written disclosure of using polyurethane for the leaflets. Both Boretos (see abstract) and Wheatley et al. (lines 48-51 of col. 2 and lines 23-29 of col. 3) teach heart valves comprising leaflets made from polyurethane in order to provide biocompatibility to implants.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by using polyurethane for the leaflets and support beams, as taught by either of Boretos and Wheatley et al., in order to provide biocompatibility to implants.

7. Claims 9,25,26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Bessler et al. US PN 5,855,601.

Schreck meets the structural limitations of claims 9,25, and 26 as described above, but lacks the express written disclosure of using nickel-titanium for the stent and the particular ranges of diameters. Bessler et al. teach in lines 3-18 of col. 6 a heart valve having a self expanding nickel titanium stent having initial diameter of about 4mm and would be capable of expanding to about 25mm in order to provide a biocompatible means of securement.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by using nickel-titanium alloys and the particular diameters for the stent, as taught by Bessler et al., in order to provide a biocompatible means of securement for the heart valve.

8. Claims 21,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Rosen US PN 4,345,340.

Schreck meets the structural limitations of claims 21,22, as described above, but lacks the express written disclosure of employing radiopaque markers on the valve. Note lines 1-3 of col. 13 describe the use of radiopaque markers, but are unclear as to whether the markers are located on the valve or delivery device. Rosen teaches in lines 19-31 of col. 2 the use of radiopaque markers on a heart valve in order to assist implantation.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by including radiopaque markers, as taught by Rosen, in order to assist the implantation procedure.

Allowable Subject Matter

9. Claims 71 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H Matthews
Examiner, AU 3738
2-6-06